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14. ABSTRACT

The second year (2007) of ProCEED study funding was dedicated to subject enrollment. Interim results are available for most parameters except those that were planned to be analyzed at study end. At the end of the reporting period, there were 62 patients enrolled (56 prostate cancer cases and 6 controls). Among the 62 patients, there was a 79% subject retention rate for the dietary follow-up calls. Interim analyses indicate that the study sample thus far is elderly, obese, and predominantly African-American. Among the prostate cancer cases most of the cases were diagnosed in stage T2 and had Gleason scores of 7 or less. The most frequently used prostate cancer treatment was hormonal therapy. The third year (2008) of funding will be dedicated to: continued subject enrollment, dietary analyses, laboratory assays, statistical analysis, and a written summary.

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Prostate cancer, epidemiology, race, lifestyle risk factors

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INTRODUCTION:

Prostate cancer has a huge and growing burden of disease, yet its natural history has not been fully elucidated. Further, it is unknown why African-American men have the highest incidence rates in the world. The ***overall goals of the ProCEED pilot study*** are: 1) to advance the understanding of the IGF axis and its interplay with race/genetics and dietary/lifestyle risk factors for prostate cancer, 2) To elucidate modifiable risk factors which interact with genetics and possibly lead to a greater incidence of prostate cancer among African-Americans, and 3) to disseminate learned information in an effort to prevent disease. It is hypothesized that racial differences in prostate cancer risk are attributed, in part, to interactions between lifestyle factors and the IGF axis. This study examines subsets of African American and Caucasian men in an attempt to elucidate dietary and lifestyle risk factors which may operate/interact uniquely in African Americans. If there are lifestyle risk factors for prostate cancer which can be modified, this would be valuable information for primary and perhaps secondary prevention of prostate cancer.

BODY:

The second year of this study was dedicated 100% to subject enrollment. Interim results are available for most parameters except those that were planned to be analyzed at the end of the study. No interim statistical tests have been performed because there was a disproportionate number of cases and controls enrolled at the end of the reporting period.

RESEARCH ACTIVITIES AND STATEMENT OF WORK

Below is the approved statement of work with updates and changes described:

Task 1. Identification/Recruitment participants (cases and controls) – Ongoing until month 30

Subject Enrollment

During the second year of the grant, recruitment was the main focus. At the end of the reporting period (11-30-06 to 11-30-07), there were 62 patients enrolled (56 prostate cancer cases and 6 controls). The goal was enroll some prostate cancer cases first to enable frequency matching of the controls on age. Cases and controls were enrolled from the Jesse Brown VA Medical Center (JBVAMC).

The recruitment strategy at JBVAMC is as follows: the MDs, clinical pharmacists, nurse practitioners, residents, and medical students in the general urology clinic all have a 3x5" index card with the ProCEED inclusion/exclusion criteria written on it. When a patient meets criteria, they automatically ask the subject if they would be interested in hearing more about the study, and they send them to the PI who then goes over the informed consent. The plan is to continue recruiting both cases and controls in 2008.

Table 1 (below) presents a listing of the subjects enrolled into the study:

Table 1. ProCEED Pilot Study Enrollment during the Annual Reporting Period: 11/30/2006- 11/30/2007*

ID	Case/Control Status	Enrollment Date	RACE	AGE
CS1103	Case	12/8/2006	Caucasian	54
CS1104	Case	12/13/2006	Caucasian	73
CS1105	Case	12/13/2006	African-American	67
CS1106	Case	12/20/2006	African-American	57
CS1107	Case	12/20/2006	African-American	72
CS1108	Case	12/22/2006	African-American	72
CS1109	Case	1/23/2007	African-American	84
CS1110	Case	1/23/2007	African-American	86
CS1111	Case	1/23/2007	Caucasian	62
CS1112	Case	1/30/2007	African-American	75
CS1113	Case	1/30/2007	African-American	71
CS1114	Case	1/31/2007	African-American	64
CS1115	Case	1/31/2007	African-American	79
CS1116	Case	2/6/2007	African-American	71
CS1117	Case	2/6/2007	African-American	62
CS1118	Case	2/7/2007	African-American	79
CS1119	Case	2/20/2007	African-American	86
CS1120	Case	2/21/2007	African-American	85
CS1121	Case	2/27/2007	African-American	85
CS1122	Case	2/27/2007	African-American	83
CL5123	Control	3/6/2007	African-American	54
CS1124	Case	3/7/2007	African-American	83
CS1125	Case	3/28/2007	Caucasian	72
CS1126	Case	4/3/2007	African-American	73
CS1127	Case	4/17/2007	African-American	64

Table 1. ProCEED Pilot Study Enrollment during the Annual Reporting Period: 11/30/2006- 11/30/2007 (CONT.)

ID	Case/Control Status	Enrollment Date	RACE	AGE
CS1128	Case	4/24/2007	African-American	75
CS1129	Case	4/25/2007	African-American	59
CS1130	Case	5/9/2007	African-American	81
CS1131	Case	5/29/2007	African-American	79
CS1132	Case	5/29/2007	African-American	88
CS1133	Case	5/29/2007	African-American	62
CS1134	Case	6/26/2007	Caucasian	72
CS1135	Case	6/26/2007	African-American	79
CS1136	Case	7/6/2007	Caucasian	61
CS1137	Case	7/6/2007	African-American	68
CS1138	Case	7/24/2007	African-American	58
CS1139	Case	7/20/1940	African-American	67
CS1140	Case	7/27/2007	Caucasian	51
CS1141	Case	7/30/2007	Caucasian	80
CS1142	Case	7/30/2007	African-American	71
CS1143	Case	7/31/2007	African-American	70
CS1144	Case	8/7/2007	African-American	75
CS1145	Case	8/21/2007	African-American	54
CS1146	Case	8/21/2007	African-American	73
CS1147	Case	8/21/2007	African-American	84
CS1148	Case	9/4/2007	African-American	85
CS1149	Case	9/5/2007	African-American	93
CS1150	Case	9/18/2007	African-American	63
CS1151	Case	9/25/2007	Caucasian	67
CS1152	Case	9/25/2007	African-American	88
CL1153	Control	9/28/2007	Caucasian	67
CS1154	Case	10/12/2007	African-American	80
CS1155	Case	10/12/2007	African-American	83
CL1156	Control	10/12/2007	African-American	58
CS1157	Case	10/16/2007	African-American	74
CS1158	Case	11/6/2007	African-American	60
CL1159	Control	11/6/2007	African-American	57
CL1160	Control	11/10/2007	African-American	80
CL1161	Control	11/16/2007	African-American	55
CS1162	Case	11/20/2007	African-American	91

*Subjects 1101 and 1102 were recruited in Year 1

Subject Retention

Among the 62 patients enrolled by the end of the reporting period, 49 participated in at least one follow-up dietary phone call, which is a 79% retention rate.

Three subjects (#1108, 1121, and 1130) were determined to be drop-outs when the dietitian called them for their follow-up dietary interviews, and they indicated that they did not want to participate in the interviews.

Eleven Subjects (#1106, 1107, 1112, 1113, 1124, 1128, 1134, 1140, 1145, 1153, 1154) were not able to be reached by the dietitian for their follow-up dietary phone interviews. Before deeming them lost to follow-up, the dietitian called each of these men at least 10 times and left messages to call back if there was an answering machine. We continue to try them every few months in case their availability changes.

Eligible Subjects who Declined Participation

There were ten people who declined to participate because they had a ride (the VA van service or a family member) waiting. Additionally, there were three people declined because they were not interested, and gave no specific reason.

Task 2. Data Collection, Months 2-29

When patients come in for a study visit, the following tasks will take place:

i. Informed consent
ii. Demographic interview
iii. Waist/hip circumference and height/weight measurement
iv. Blood sample
v. 24-hour dietary recall (during telephone follow-up)
vi. Work and social history questionnaire
vii. IPAQ exercise questionnaire
viii. Block Brief food frequency questionnaire (during telephone follow-up)
ix. Patient incentive given

The available preliminary data findings are presented below. The two subjects enrolled during the previous reporting period (1101 and 1102) are also included below since no data for these patients was included in the previous report.

SOCIODEMOGRAPHICS

The mean age of the enrolled subjects was 71.5 (s.d. 11.0). The subjects were predominantly African-American (82%). The mean BMI for the subject population was 30.9 (s.d. 7.6), which is considered to be obese. Approximately one fifth (19%) of the subjects were working at the time of the study visit, but the majority of the subjects were retired (71%). In terms of relationship status, 43% of the subjects reported living with a spouse or partner. About one third (34%) of the subjects reported that they currently drink alcohol at least once a week, and 27% reported current smoking. In terms of educational status, 62% of the subjects had a high school education or less.

MEDICAL HISTORY

Of the 62 subjects, 52% reported having a first degree relative with cancer, 32% reported having a first degree family member with prostate cancer. A very high proportion of the patients had hypertension (84%). The following comorbidities were also most common: hyperlipidemia (52%), erectile dysfunction (33%), Joint pain (27%), diabetes (25%), GERD (19%), arthritis (17%), colon polyps (17%), and depression (16%).

PROSTATE CANCER CLINICAL INFORMATION

Among the 53 prostate cancer cases with complete biopsy and treatment data (3 subjects were still pending at the time of this report), most subjects were diagnosed in stage T2, and had Gleason scores of 6 (41.5%) or 7 (35.8%). The breakdown of the subject Gleason scores are presented in Table 2 below:

Table 2. ProCEED Pilot Study – Prostate Cancer Gleason Scores at Biopsy

Gleason Score Category	Number of Subjects	%
5	1	1.9%
6	22	41.5%
7	19	35.8%
8	5	9.4%
9	6	11.3%

Gleason scores are given to prostate cancer based upon its microscopic appearance. The Gleason score is important because higher Gleason scores are associated with worse prognosis. This is because higher Gleason scores are given to cancer which is more aggressive.

In terms of treatment options, most subjects opted for hormonal therapy (38.5%). The percentages for the treatment options do not add up to 100% because some patients opted for combination therapy. Table 3 (below) presents the breakdown of the prostate cancer treatment options in the study sample:

Table 3. ProCEED Pilot Study – Prostate Cancer Patient Treatment Options

Gleason Score Category	Number of Subjects	%
Hormonal Therapy	20	38.5%
Radical Prostatectomy	13	13.0%
Radiation Therapy	12	23.1%
Watchful Waiting	14	27.0%
Brachytherapy	1	1.9%

DIETARY DATA FOLLOW-UP

49 of the 62 (79%) subjects participated in the follow-up dietary interviews. Of these patients, 49/49 (100%) had a Block Brief Food Frequency questionnaire, and 45/49 (92%) had at least one 24-hour dietary recall interview. The 24-hour recall information has been data-entered into the NCS dietary data entry system and will be analyzed by the study dietitian during year three (2008). The Block Brief FFQ forms will be sent to Nutrition Quest (the Block FFQ vendor) for processing in a batch at the end of the study.

Task 3. Determination of serum levels of IGF-1, IGFBP-3, PSA and testosterone, Months 2-29 (for collections and storage), Months 29-31 (for assays and data entry)

100% of the subjects provided serum samples for the study. The serum will be tested for PSA, testosterone, IGF-1, and IGFBP-3. The samples are currently stored in a -70 freezer at JBVAMC to be processed in a batch at the end of the study.

Task 4. Statistical Analyses, Months 30-36

All statistical analyses will be done at the end of the study

KEY RESEARCH ACCOMPLISHMENTS:

- Presentation at the IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting in Atlanta, GA on 9/5/2007 (APPX A)
- Study enrolled 60 additional subjects since previous report
- Study began to enroll control patients

REPORTABLE OUTCOMES:

I. Abstract / Presentation

"Racial Trends in Prostate Cancer Incidence in Illinois and the United States 1986-2000", Presented at the IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting in Atlanta, GA on 9/5/2007 (see appendix A for a copy of the poster presentation handout)

CONCLUSIONS:

The second year of this study was dedicated 100% to subject enrollment. Interim results are available for most parameters except those that were planned to be analyzed at the end of the study. No interim statistical tests were performed because there was a disproportionate number of cases and controls enrolled at the end of the reporting period.

At the end of the reporting period, there were 62 patients enrolled (56 prostate cancer cases and 6 controls). Among the 62 patients, there was a 79% subject retention rate for the dietary follow-up calls. Interim analyses indicate that the study sample thus far is elderly, obese, and predominantly African-American. Among the prostate cancer cases, the majority of subjects (~80%) had Gleason scores of 7 or less.

Year three (2008) of the grant will be dedicated to: continued subject enrollment, dietary analyses, laboratory assays, statistical modeling, and a written summary of the final results.

REFERENCES:

1) Wallace, KL, Furner SE, Freeman, VF and Davis FM. Racial trends in prostate cancer incidence rates for Illinois and the United States; 1986-2000. Poster presented at the IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting in Atlanta, GA on 9/5/2007.

APPENDIX A – IMPaCT POSTER PRESENTATION:

UIC SCHOOL OF PUBLIC HEALTH
UNIVERSITY OF ILLINOIS AT CHICAGO
Epidemiology and Biostatistics Division

Racial trends in prostate cancer incidence rates for Illinois and the United States; 1986-2000

Katrine Wallace MA, Sylvia Furner PhD, Vincent Freeman MD MPH, Faith Davis PhD

INTRODUCTION

The 1988 introduction of PSA screening led to an increase and subsequent decrease in US prostate cancer incidence[1]. Compared to other US cancer registries, Illinois has been reported to have lower prostate cancer rates[2]. The objective of this study was to examine trends in Illinois and US prostate cancer rates to ascertain whether trends were similar by race.

METHODS

Incidence rates were obtained from Illinois State Cancer Registry[3] and SEER[4]. Rate ratios were estimated for three periods: 1986-1990 ("pre-PSA"), 1991-1995 ("PSA-uptake"), and 1996-2000 ("PSA-widespread use"). 95% Confidence intervals were calculated using PEPI version 4.0[5]. Age-adjusted rates are presented by year, race and region.

RESULTS

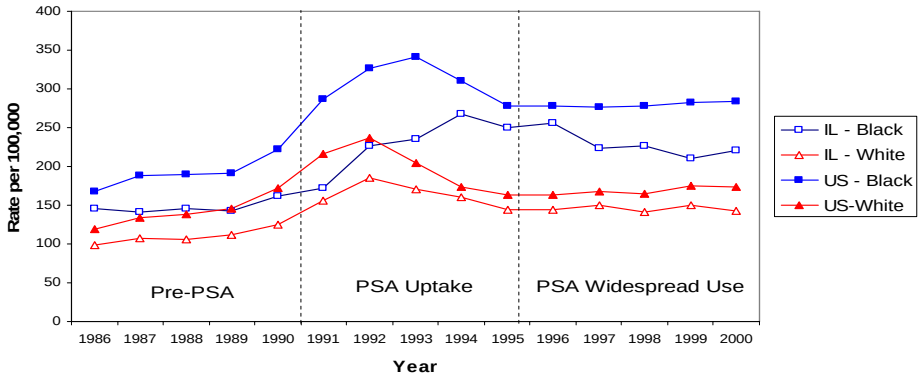
Incidence rates peaked in the mid-1990s. Illinois had lower rates for every time period under study in both race groups. Rate differences between the two regions narrowed in 1994 and 1995. African-Americans had higher incidence rates than Caucasians throughout. The post-1996 incidence pattern in Illinois, however, was unique with the incidence rates in African-Americans declining and the racial disparities narrowing.

Prostate Cancer Incidence Measures for Illinois and the United States: Pre-PSA (1986-1990), PSA-Uptake (1991-1995) and PSA-Widespread Use (1996-2000) Periods

Years	Caucasians RR (CI)*	African-Americans RR (CI)*	IL Caucasian Incidence Rates per 100,000 (CI)**	IL African-American Incidence Rates per 100,000 (CI)**	US Caucasian Incidence Rates per 100,000 (CI)***	US African-American Incidence Rates per 100,000 (CI)***
1986-1990	0.78 (0.60-.99)	0.76 (0.62-0.95)	110 (108-112)	148 (142-153)	142 (141-144)	193 (187-198)
1991-1995	0.82 (0.67-1.01)	0.75 (0.63-0.89)	163 (161–165)	231 (225-238)	198 (197-199)	308 (302-315)
1996-2000	0.86 (0.69-1.07)	0.81 (0.68-0.97)	145 (144-147)	227 (221-233)	169 (168-170)	280 (275-285)

*Sources: Illinois Department of Public Health, Illinois State Cancer Registry, SEER, National Cancer Institute
**Source: Illinois Department of Public Health, Illinois State Cancer Registry, Incidence rates are adjusted for age
*** Source: SEER, National Cancer Institute, Incidence rates are adjusted for age

Prostate Cancer Incidence Rates by race for United States and the State of Illinois, 1986-2000



CONCLUSION

These results suggest that more effective prostate cancer screening is taking place in Illinois African-American populations than US African-American populations, although differential risk profiles may also be operating.

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1) Parkin DM, Bray FI, Devesa SS. Cancer burden in the year 2000. The global picture. *European Journal of Cancer.* 2001;37(Supplement 8):4.
2) Howe H, ed. *Cancer Incidence in North America 1988-1991*. Sacramento, CA: North American Association of Cancer Registries; 1995.
3) Illinois Department of Public Health I. Illinois State Cancer Registry; 2005.
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